

Notice of Allowability

Application No.

09/893,344

Applicant(s)

EISENBACH-SCHWARTZ ET AL.

Examiner

Christopher J Nichols, Ph.D.

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 31 March 2004.
2. ☒ The allowed claim(s) is/are 32,34,40 and 64-66.
3. ☒ The drawings filed on 7 July 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Response and Amendment filed 31 March 2004 has been received and entered in full.
2. Newly submitted claims **67-80** are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the invention of claims 67-80 is drawn to a method causing T cells activated by poly-Glu,Tyr to accumulate at the site of RGC death/or optic nerve damage by one of several means including but not limited to administration of poly-Glu,Tyr activated T cells, classified in class 435, subclass 455. The claims which were under examination were drawn to a method of administering poly-Glu,Tyr as a therapeutic classified in class 514, subclass 2. In addition, a search of the administration of activated T cells would cover the art of therapeutic cell administration that is not co-extensive with therapeutic peptides. Therefore, the two sets of claims are in separate classifications and different arts, are not linked as to share a common search.
3. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims **67-80** are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

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Allowable Subject Matter

4. All Rejections and Objections as set forth in the previous Office Action (3 December 2003) are hereby *withdrawn* in view of Applicant's submissions and amendments (31 March 2004).
5. Pursuant to MPEP §706.07(e) in view of Applicant's amendments (31 March 2004), the finality of the previous Office Action (21 January 2004) is hereby *withdrawn*.

EXAMINER'S AMENDMENT

6. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

In the claims:

Claims 1-31 (Cancelled)

Claim 32 (Currently Amended) A method for lessening retinal ganglion cell (RGC) death and/or lessening damage to the optic nerve arising from a condition selected from the group consisting of glaucoma, increased intraocular pressure and glutamate toxicity, comprising:

administering to an individual in need of such treatment an effective amount of poly-Glu,Tyr, in such a manner as to cause a T cell response thereto, such that T cells become

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~~activated by the poly-Glu,Tyr~~, thereby lessening RGC death and/or lessening damage to the optic nerve.

Claim 33 (Cancelled)

Claim 34 (Previously Presented) A method in accordance with claim 32, where said individual in need is one whose damage to the optic nerve is caused or exacerbated by glutamate toxicity.

Claims 35-39 (Cancelled)

Claim 40 (Previously Presented) A method in accordance with claim 32, wherein said individual in need is one whose damage to the optic nerve arises from abnormally elevated intraocular pressure.

Claims 41-63 (Cancelled)

Claim 64 (Previously Presented) A method in accordance with claim 32, where said individual in need is one whose damage to the optic nerve arises from glaucoma.

Claim 65 (Currently Amended) A method in accordance with claim 32, wherein said administration of an effective amount of poly-Glu,Tyr to said individual in need ~~is one in need of~~ causes lessening of RGC death.

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Claim 66 (Currently Amended) A method in accordance with claim 32, wherein said administration of an effective amount of poly-Glu,Tyr to said individual in need is one in need of causes both lessening of RGC death and lessening damage to the optic nerve.

Claims 67-80 (Cancelled)

7. Authorization for this examiner's amendment was given in a telephone interview with Roger Browdy (Reg. No. 25,618) on 28 April 2004.

Summary

8. Claims 32, 34, 40, 64, 65, and 66 are hereby allowed.

9. The Examiner acknowledges that acceptance of the above Examiner's Amendment does not mitigate in any way, shape, or form, Applicant's right to pursue additional subject matter in continuation, continuation-in-part, and/or divisional applications pursuant to 35 U.S.C. §120 and §121.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on **(571) 272-0887**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN

April 28, 2004



ELIZABETH KEMMERER
PRIMARY EXAMINER